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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,782

08/16/2006

Shinobu Fujimura

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EXAMINER

SAYALA, CHHAYA D

ART UNIT

PAPER NUMBER

1781

NOTIFICATION DATE

DELIVERY MODE

05/27/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,782	<b>Applicant(s)</b> FUJIMURA ET AL.	
	<b>Examiner</b> C. SAYALA	<b>Art Unit</b> 1781	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/26/07; 2/21/06</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for poultry, does not reasonably provide enablement for all livestock that would include poultry and both monogastric and ruminants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue.” These factors include, but are not limited to the following factors set forth in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1998) as appropriate. See also MPEP § 2164.01(a) and § 2164.04.

These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;

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- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention

based on the content of the disclosure.

The specification does not enable one of ordinary skill in the art to properly extrapolate the feeding of diets with lowered Leucine content intended for poultry to animals and livestock of all kinds such as fish, cows, horses, pigs, etc. Therefore, there is little if any direction given with regards to what leucine content would be required to increase glutamic acid or if glutamic acid is increased at all. The article by Zhou et al. ("Regulation of glutamate dehydrogenase by branched-chain amino acids in skeletal muscle from rats and chicks", Int. J. Biochem. Cell Biol., vol. 28(7), pages 787-793, 1996) underscores the fact that the lowered Leucine content brings different results to different species. For instance, GDH activity was stimulated by Leu and IsoLeu in rats and Leu in chicks. Since the result of lowering Leu and increasing glutamic acid is dependent on GDH activity and this reference shows that GDH activity is stimulated differently in different animals, it can be reasonably expected that the increase of glutamic acid cannot be expected to be the result in all animals when Leu is decreased. Therefore, the amount of experimentation necessary to use the invention for all types of livestock as mentioned above, based on the content of the disclosure would be high and would constitute an undue burden.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “a” feed with “low” leucine content. First, “low” is of indeterminate scope. The specification does not define this term. With regard to the term “high”, it has been well established that “high” is vague and the art knows no definite meaning of “high”. “High” renders the claims ambiguous inasmuch as specification neither sets forth a range nor defines the limits, scope, and meaning of relative term “high”. See *Ex parte Powell*, 155 USPQ 104; *B.B. Chemical Co. v. Cataract Chem. Co., Inc.*, 50 USPQ 530. **The same standard applies to “low”.**

With regard to claim 5, which depends from claim 1, while claim 1 recites “a” feed, claim 5 recites two feeds for two sets of poultry, and is indefinite in not further limiting claim 1.

In claim 1, applicant recites a feed having a “low leucine content” and yet in claims 2-3, 6-7, the amounts of leucine recited exceed **100% of “leucine requirement”**.

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First, it is not clear what defines the terms “leucine requirement”. Next, it is not clear how the claims can recite an amount over 100% of leucine requirement and yet, claim 1 states **a low leucine content**. The claims are confusing and unclear.

### ***Claim Objections***

3. Claim 8 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Imanari et al. (cited by applicant)

The reference discloses 4 week chicks with adjusted leucine levels in amounts as claimed, wherein Glu increased significantly in the flesh of the chicken.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imanari et al. in view of Nutrient Requirements of Poultry (NRC, 1994, page 20)

Imanari is as described above for claim 1. Claim 4 recites lowering levels of Leu for chicks 6 weeks and over. Since Imanari discloses amounts of Leu reduction for 4 week chicks, based on this, to reduce leucine contents in the feed to achieve the same result in the same animal/bird, that is increasing Glu in the flesh of the chicken, would have been within the skill of the person of ordinary skill in the art. Imanari does not describe the crude protein content of the feed, however, NRC requirements for poultry younger than 6 weeks and older than 6 weeks is given at page 20, amounts that coincide with the amount claimed.

6. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farran et al. (1992 and 1990) (both cited by applicant) in view of Zhou et al. (Int. J. Biochem. Cell Biol., vol. 28(7), pages 787-793, 1996) and further in view of Aoki et al. (J. Clin. Invest., vol. 68, pp. 1522-28, 1981).

Farran (1992) describes Leu amounts in feeds for 3 week old chicks that resulted in increased feed conversion and weight gain. Farran (1990) describes Leu feeding for chicks that are 3 weeks old and concludes that the maximum requirement for Leucine in chicks is 1.16% of the dietary requirement, which obtained optimum growth. Both Farran references do not describe lowered Leu increased glutamine synthesis in the

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chick. Zhou et al. teach that Leu increased GDH activity, (page 789, second col.) and leucine regulates glutamine synthesis in the muscle. Note the crude protein amount disclosed at col. 2, page 761. To incorporate such amounts of crude protein in the diet of the birds would have been prima facie obvious. Aoki teaches that feeding a Leucine meal increased Glu. Based on the percentages of Leucine claimed herein, it would have been obvious to the person of ordinary skill in the art that glutamine would have increased in the chicks disclosed by Farran, when fed Leucine. This conclusion would have been equally applicable to 6 week chicks as well, based on the references applied, and the artisan would have reasonably expected such.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Sayala, whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO



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Customer Service Representative or access to the automated information system, call  
800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/C. SAYALA/**

**Primary Examiner, Art Unit 1781**